

Billing Code 4410-09-M

DEPARTMENT OF JUSTICE DRUG ENFORCEMENT ADMINISTRATION MANUFACTURER OF CONTROLLED SUBSTANCES NOTICE OF REGISTRATION CAMBREX CHARLES CITY, INC.

By Notice dated July 17, 2012 and published in the Federal Register on July 26, 2012, 77 FR 43863, Cambrex Charles City, Inc., 1205 11th Street, Charles City, Iowa 50616, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Drug	Schedule
Gamma Hydroxybutyric Acid (2010)	I
Amphetamine (1100)	II
Lisdexamfetamine (1205)	II
Methylphenidate (1724)	II
4-Anilino-N-phenethyl-4-piperidine (ANPP)(8333)	II
Phenylacetone (8501)	II

Drug	Schedule
Cocaine (9041)	II
Codeine (9050)	II
Oxycodone (9143)	II
Hydromorphone (9150)	II
Hydrocodone (9193)	II
Methadone (9250)	II
Dextropropoxyphene, bulk (non-dosage forms) (9273)	II
Morphine (9300)	II
Oripavine (9330)	II
Thebaine (9333)	II
Opium, raw (9600)	II
Opium extracts (9610)	II
Opium fluid extract (9620)	II
Opium tincture (9630)	II
Opium, powdered (9639)	II
Opium, granulated (9640)	II
Oxymorphone (9652)	II
Noroxymorphone (9668)	II
Poppy Straw Concentrate (9670)	II
Alfentanil (9737)	II
Remifentanil (9739)	II

Drug Schedule

Sufentanil (9740) II

Fentanyl (9801) II

The company plans to manufacture the listed controlled substances in bulk for sale to its customers, for dosage form development, for clinical trials, and for use in stability qualification studies.

No comments or objections have been received. DEA has considered the factors in 21 USC § 823(a), and determined that the registration of Cambrex Charles City, Inc., to manufacture the listed basic classes of controlled substances is consistent with the public interest at this time. DEA has investigated Cambrex Charles City, Inc., to ensure that the company's registration is consistent with the public interest. The investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with state and local laws, and a review of the company's background and history.

Therefore, pursuant to 21 USC § 823(a), and in accordance with 21 CFR § 1301.33, the above named company

is granted registration as a bulk manufacturer of the basic classes of controlled substances listed.

Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control
Drug Enforcement Administration

DATED: November 14, 2012

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